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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,914	08/21/2003	Mark Howansky	GYN5005	9281

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EXAMINER

SUHOL, DMITRY

ART UNIT PAPER NUMBER

3714

DATE MAILED: 01/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

8W

Office Action Summary	Application No.		Applicant(s)	
	10/645,914		HOWANSKY ET AL.	
	Examiner		Art Unit	
	Dmitry Suhol		3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☒ Claim(s) 1 and 16 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

Claims 1 and 16 are objected to because of the following informalities:

Regarding claim 1, portion of line 7 reads "...a housing having a having a first end..." it would appear that it should read "...a housing having a first end...". Portion of line 8, reads "...and an outlet,;" it would appear that the comma is not needed. Portion of line 12 reads "...within the channel and exerted on..." it would appear that it should read "...within the channel exerted on...".

Regarding claim 16, portion of line 17 reads "...housing having a having a channel..." it would appear that it should read "...housing having a channel..."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 contains the trademark/trade name Teflon. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second

paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a polymer with the chemical name of polytetrafluoroethylene and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-10, 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Stevenson et al '631. Stevenson discloses a relief valve containing all of the elements of the claims including with reference to claims 1, 12 and 16, providing a housing (10 and 18) having a first end (inlet 14), a second end (end containing plug 31), and a channel therethrough extending between an inlet at the first end of the housing and an outlet (exit 16 shown in figures 2 and 3); a plug member (obstruction member as required by claim 12) positioned within the channel (23) and being sized and shaped to substantially occlude the channel at a predetermined location when a predetermined

Art Unit: 3714

force is exerted on a first side thereof (figures 2 and 3), the plug/obstruction member further being movable within the channel so that, when a fluid force within the channel exerted on a second opposite side of the plug member exceeds the predetermined force, the plug member no longer occludes the channel (page 1, col. 2, lines 36-41); an adjustment member movably coupled to the housing (plug 31); and a compression member (means for exerting a predetermined force on the obstruction member as required by claim 12) positioned within the channel in a compressed state so that a first end exerts force on the plug member and a second end exerts force on the adjustment member (spring 28), wherein the adjustment member is movable relative to the housing to thereby adjust the amount by which the compression member is compressed (page 1, col. 2, lines 21-23 and lines 36-39). The adjustment member being movable relative to the housing so that the predetermined force exerted by the compression member on the plug member can be selected to be any force in a physiological range substantially corresponding to the range of forces required to force open the urethral sphincter of a human patient, as required by claims 2 and 12, is pointed to at page 2, col. 1, lines 15-18 where it is clear that the predetermined force may be adjusted as wished by the user. The adjustment member being movable relative to the housing so that the predetermined force exerted by the compression member on the plug member can be selected to correspond to any pressure on the plug member within the range of approximately 20 to 180 mm Hg, as required by claims 3 and 13, is pointed to at page 2, col. 1, lines 15-18 where it is clear that the predetermined force may be adjusted as wished by the user. 4. The channel includes a first channel portion (14) extending

Art Unit: 3714

inwardly from the housing inlet and a second channel portion in fluid communication with the first channel portion and with the housing outlet (chamber 11), and having a larger cross-section than the first channel portion, as required by claim 4, is shown in figures 2 and 3. The outlet comprising at least one aperture extending from the second channel portion laterally through the housing, as required by claim 5, is shown as exit 16 in figure 2. An opening at the distal end of the housing extending into the second channel portion, as required by claims 6-7 and 15, is shown as the opening containing adjustment member 31 which is threadably engaged therewith (page 1, col. 2, lines 18-19) in figures 2 and 3. A transition zone, as required by claim 9, is shown in figures 2 and 3 as beveled seat 13 where it is clear that the beveled seat and the first end (beveled bottom edge 25) of the plug member (piston 23) have a substantially complementary configurations. An inflow port, as required by claim 10, is shown as conduit 15 in figure 2. A means for exerting force comprising a compression member (spring 28) and an adjustment member (plug 31), as required by claim 14, are shown in figures 2 and 3 and their respective relationship described at page 1, col. 2, lines 36-38.

Regarding claim 16, the step of moving the adjustment member relative to the housing until the compression member exerts the predetermined force on the plug is inherent in the device of Stevenson since the valve is set to a predetermined pressure force as required by the user (page 2, col. 1, lines 15-18), while the step of infusing fluid into the channel so to exert pressure on the second side of the plug member using an infusion device until the force of the infused fluid against the plug member exceeds the predetermined force is described at page 1, cols. 1-2, lines 47+ and line 1, respectively.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevenson et al '631 in view of Mathys '930. Although Stevenson discloses all of the elements of the claims, as stated above, the reference fails to teach a locking member as required by claim 8. However Mathys discloses a relief valve, like that of Stevenson, which further teaches the use of a locking member (21) to secure an adjustment member (20) in place (see col. 2, lines 24-29). Therefore it would have been obvious to one having ordinary skill in the art at the time of the claimed invention to have provided the device of Stevenson with a locking member to hold the adjustment securely in position.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevenson et al '631 in view of Butterfield '018. Stevenson discloses all of the elements of the claims, as stated above, but for a plug member comprised of a material selected from the group consisting of Teflon, polyethylene, polyurethane, and silicone, however Butterfield discloses a relief valve like that of Stevenson which clearly teaches that it is

Art Unit: 3714

known to provide such a device with a plug/plunger/piston comprised of a Teflon material for the purpose of durability (col. 3, lines 31-37). Therefore it would have been obvious to manufacture the device of Stevenson with a plug/plunger/piston portion comprised of a Teflon material for the purpose of durability and long life.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dmitry Suhol whose telephone number is 571-273-4430. The examiner can normally be reached on Mon - Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Derris Banks can be reached on 703-308-1745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ds

Dmitry Suhol
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